

REMARKS

Claims 1, 3-11 are pending. Claim 2 has been withdrawn as assertedly directed to non-elected subject matter. Claims 1, 2, 6 and 11 have been amended. No new matter has been added. Claims 12-17 have been cancelled without prejudice or disclaimer to the subject matter to which they pertain. Applicants respectfully reserve the right to file continuing applications.

Applicants gratefully acknowledge the Examiners' reconsideration and withdrawal of the 35 U.S.C. §102 rejection to claim 1-11 in view of Millar et al.

Formalities

Applicants respectfully submit that the claim amendments are in proper format with regard to the claim status identifiers pursuant to M.P.E.P. §714 II.C. (A).

Objections

Claim 2 is objected to for assertedly including subject matter which has been non-elected due to a restriction requirement; and therefore, assertedly withdrawn from consideration. Applicants traverse this withdrawal to the extent it applies to the herein presented claim 2. Claim 2 depends from claim 1 and claims variants reduced to practice and tested for plant insulator activity. In particular, claim 2 is directed to the variants which hybridize to the complement of SEQ ID NO:9 under 5X SSC and 42°C wash conditions and have plant genetic insulator activity. Applicants request reconsideration and withdrawal of the denial to examine a reasonable number of nucleotides, and request examination of a reasonable number of nucleotide sequences pursuant to M.P.E.P. §803.04 in view of the amended claims.

Rejections Under 35 U.S.C. §101

Claims 6 and 7 remain rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter because of the non-entry of the previously presented claim amendments. Applicants traverse this rejection for the reasons of record and for at least the following reasons. Claim 6 and 7 are directed to a host cell comprising the replicable vector of claim 3. Applicants respectfully submit that a host cell, plant or otherwise, transfected with a vector comprising an isolated gene does not occur in nature. Accordingly, Applicants respectfully submit that the

claimed invention is directed to statutory subject matter and requests reconsideration and withdrawal of the rejection.

Rejections Under 35 U.S.C. §112, second paragraph

Claims 1-11 remain rejected under 35 U.S.C. §112, second paragraph (indefiniteness), as allegedly being indefinite because the of the non-entry of the previously presented claim amendments to claims 1 and 11 in the December 1, 2004 Amendment. In particular, the Office Actions assertedly finds the phrase “its complement” unclear in regard to what it refers to. Applicants respectfully traverse this rejection to the extent it applies to the herein claimed invention. Claims 1 and 11 have been amended to state, “wherein said variant hybridizes to the complement of SEQ ID NO:9”. Further, it is respectfully submitted that one of ordinary skill in the art would understand the meaning of “complement of SEQ ID NO:9” in the context of nucleic acids to be the respective nucleotide sequence formed by purine/pyrimidine base pairing to SEQ ID NO:9. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections Under 35 U.S.C. §112, first paragraph

Claims 1- 11 are rejected under 35 U.S.C. §112, first paragraph (written description), as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent it applies to the herein claimed invention, for the reasons of record set forth in the December 1, 2004 Amendment and for at least the following reasons.

Contrary to the Advisory Actions assertions, Applicants have described a reasonable genus of variants of SEQ ID NO:9 to show that the inventor had possession of the invention at the time of filing. According to the standards set forth in the United States Patent and Trademark Office Guidelines, Synopsis of Application of Written Description Guidelines, available at <http://www.uspto.gov/web/patents/guides.htm>, *Id.* citing 66 Fed. Reg 1099 (January 5, 2001) (“The Guidelines”), which have been adopted by the Federal Circuit in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002), the written description requirement for biomolecules is met by:

show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or **some combination of such characteristics**.

Guidelines, *Id.* citing 66 Fed. Reg. at 1106 (emphasis added). Specifically, the court in *Enzo* adopted the Guidelines with respect to defining the structure of a nucleic acid on the basis of hybridization to a disclosed sequence consistent with the with Example 9 of the Guidelines. *Enzo* 323 F.3d at 968. Example 9 requires: 1) that a genus be defined such that the skilled artisan would not expect much structural variation within the genus and 2) that genus be limited by a required function related to the structure of the specific member of the genus. Example 9 concludes that with respect to its exemplary claim:

[A] person of skill in the art **would not expect substantial variation** among species encompassed within the scope of the claims [sic] because highly stringent conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, **since highly stringent hybridization conditions in combination with the coding function of DNA** and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention. [emphasis added]

Guidelines at 35-37. Thus, the Guidelines provide that the written description requirement would be met by claims reciting high stringent hybridization conditions in combination with a functional requirement where there is a relationship between structure and the relevant function.

The claimed invention meets the Guidelines for written description. A person of skill in the art is able to glean from the written description the genus of variants using known methods, and the nucleic acid sequence of SEQ ID NO:9, the stringent hybridization conditions and insulator activity provided by Applicants. Accordingly, Applicants respectfully submit that there is written description of the claimed invention and Applicants respectfully request reconsideration and withdrawal of the rejection.

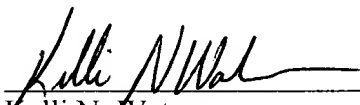
CONCLUSION

Early consideration, entry of the Amendment and Reply, favorable consideration and prompt allowance of the pending claims are respectfully believed to be in order and respectfully requested. If anything else is necessary to place this application in condition for allowance, e.g., by Examiner's Amendment, Applicant respectfully requests that the Examiner contact the undersigned representative at the telephone number listed below.

To the extent necessary, please grant any extension of time deemed necessary for entry of this communication. Please charge any deficient fees, or credit any overpayment of fees, to Deposit Account 500417.

Respectfully submitted,
McDERMOTT, WILL & EMERY LLP

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By: 
Kelli N. Watson
Registration No. 47,170

600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8351 (Direct)
(202) 756-8087 (Facsimile)

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